

Appl. No. 10/051,952
Reply to Office Action of June 2, 2005

Remarks

Introduction

Claims 1-4, 10, 12, 36-39, and 43-45 were pending. By way of this response, claim 1, 36, and 45 have been amended. Support for the amendments to the claims can be found in the application as originally filed, and no new matter has been added. For example, methods for treating conditions other than hyperhydrosis can be found at least at page 13, line 5. Accordingly, claims 1-4, 10, 12, 36-39, and 43-45 remain pending.

In view of the amendments and remarks herein, applicant requests reconsideration of the rejections.

Rejections Under 35 U.S.C. § 103

Claims 1, 2, 10, 12, 36, 37, and 43-45 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Borodic (U.S. Patent No. 5,183,462) taken with Vadoud-Seyedi et al. (hereinafter Vadoud) and Slate et al. (U.S. Patent No. 6,645,169; hereinafter Slate). Claims 3, 4, 38, and 39 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Borodic in view of Vadoud and Slate, and further in view of McCabe (U.S. Patent No. 5,525,510).

Applicant traverses the rejections, especially as they relate to the present claims.

The present claims recite that the botulinum toxin is administered to a human subject using a needleless syringe

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having a pressure sufficient to deliver the botulinum toxin to a muscle tissue associated with a wrinkle or brow furrow to reduce a muscle contraction of the muscle tissue without treating hyperhydrosis of the human subject.

Vadoud discloses needleless injection of a botulinum toxin to the soles of the feet of 3 patients to treat the glandular condition of plantar hyperhidrosis. Vadoud discloses that needleless injections of botulinum toxin into the palms to treat palmar hyperhidrosis is not recommended because of possible injury to superficial palmar nerves or vessels. Vadoud does not disclose any characteristics of the needleless syringe or the method of administration, let alone a method of treating wrinkles or brow furrows in a patient.

Applicant submits that the present claims are patentable over the combination of Borodic, Vadoud, and Slate since the combination of references fails to disclose, teach, or suggest all of the elements recited in the present claims. For example, the combination of references fails to disclose, teach, or even suggest administration of a botulinum toxin using a needleless syringe having a pressure sufficient to deliver a botulinum toxin to a muscle tissue associated with a wrinkle or brow furrow to reduce a muscle contraction of the muscle tissue without treating hyperhydrosis of the human subject, as recited in the present claims.

In contrast, applicant submits that combination of references actually teaches away from the present claims since the only reference disclosing needleless injection of botulinum toxin (i.e., Vadoud) discloses administration of botulinum toxin

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to the soles of feet of patients to treat sweat glands associated with plantar hyperhidrosis. As discussed in applicant's previous responses, sweat glands which are treated by Vadoud are located in the dermal layer of the skin. As discussed in the specification of the above-identified application, muscle tissue is located inwardly and away from the dermal layer. Thus, Vadoud discloses needleless administration of a botulinum toxin to a different and distinct target site than that recited in the present claims.

Thus, the combination of references, when taken as a whole, discloses that needleless injection of a botulinum toxin may be effective in treating plantar hyperhidrosis. However, this combination of references does not disclose or even suggest needleless injection of a botulinum toxin to treat a condition, such as a wrinkle or brow furrow, without treating hyperhidrosis, as recited in the present claims. Therefore, the combination of Borodic, Vadoud, and Slate does not disclose, teach, or even suggest all of the elements recited in the present claims.

In addition, applicant submits that a person of ordinary skill in the art would not be motivated to combine the references, let alone to do so and obtain the presently claimed methods. For example, a person of ordinary skill in the art given the teachings of Borodic would not be motivated to even consider the teachings of Vadoud, which is only concerned with treatment of hyperhidrosis, when considering a treatment for wrinkles or brow furrows without treating hyperhidrosis, as recited in the present claims.

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Furthermore, applicant submits that a person of ordinary skill in the art would not be motivated to use a needleless injector to administer a botulinum toxin to a patient to treat a wrinkle or brow furrow given the teachings of Borodic and Vadoud because Vadoud specifically teaches that the sole of the foot is a special target region in which the nerves are located at deeper regions than other regions of the body, such as the palm of the hand. As discussed herein, Vadoud specifically states that needleless injection of botulinum toxin is not recommended for administration to the palm of the hand due to the superficial location of the palmar nerves and vessels. Thus, the sole of the foot represents a special administration site represented by a thick layer of tissue covering the nerves. Other regions of the body where wrinkles and brow furrow occur, such as facial regions, do not have a thick layer of tissue covering nerves, and therefore, the benefits of treating plantar hyperhydrosis by needleless injection of botulinum toxin into the sole of the foot would not motivate a person of ordinary skill in the art to use needleless injection to administer a botulinum toxin to other (e.g., non-foot) regions of the body. This is further supported by the fact that Vadoud specifically teaches away from using needleless injection techniques of botulinum toxin in regions other than the sole of the foot.

Since the combination of Borodic, Vadoud, and Slate does not disclose, teach, or suggest all of the elements of the present claims, and since a person of ordinary skill in the art would not be motivated to combine these references, applicant submits that the present claims, and claims 1, 2, 10, 12, 36, 37, and 43-45 in particular, are unobvious from and patentable over Borodic, Vadoud, and Slate under 35 U.S.C. § 103.

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Regarding the rejection of claims 3, 4, 38, and 39 over Borodic in view of Vadoud and Slate, and further in view of McCabe, applicant submits that McCabe fails to resolve the deficiencies of the combination of Borodic, Vadoud, and Slate. For example, McCabe does not disclose, teach, or even suggest administration of a botulinum toxin using a needleless syringe having a pressure sufficient to deliver the botulinum toxin to a muscle tissue associated with wrinkles or brow furrows to reduce a muscle contraction of the muscle tissue without treating hyperhydrosis of the human subject, as recited in the present claims. Since the combination of Borodic, Vadoud, Slate and McCabe fails to disclose, teach, or even suggest all of the elements recited in the present claims, applicant submits that the present claims, including claims 3, 4, 38, and 39, are unobvious from and patentable over Borodic, Vadoud, Slate and McCabe under 35 U.S.C. § 103.

In addition, each of the additional present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In view of the above, applicant submits that the present claims, that is claims 1-4, 10, 12, 36-39, and 43-45, are unobvious from and patentable over Borodic, Vadoud, Slate, and McCabe, in any combination under 35 U.S.C. § 103.

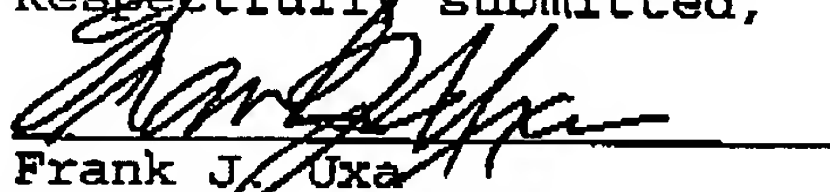
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Conclusion

In conclusion, applicant has shown that the present claims are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-4, 10, 12, 36-39, and 43-45 are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: 10/3/05

Respectfully submitted,



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